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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,400	04/07/2006	Jouko Savolainen	LOYZ 2 00005	8987

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EXAMINER	
TSAY, MARSHA M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,400	SAVOLAINEN ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11-16,18-27 and 30-34* is/are pending in the application.

4a) Of the above claim(s) *6-8 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,11-16,18-26 and 30-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election without traverse of Group I, claims 1-5, 11-16, 18-26, 30-34 in the reply filed on August 31, 2007 is acknowledged.

Claims 9-10, 28-29 are canceled. Claims 6-8, 27 have been withdrawn from further consideration by the Examiner because they are drawn to non-elected inventions. Claims 1-5, 11-16, 18-26, 30-34 are currently under examination.

Priority: The benefit date is October 15, 2003 for the purpose of prior art.

Claim Objections

Claim 24 is objected to because of the following informalities: in claim 24, the multiple "or"[s] should be deleted, only one "or" should be inserted between "combinations thereof". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 11-16, 18-26, 30-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a protein-based film to form from an interchange reaction at pH 3.5-7.0, does not reasonably provide enablement for a protein-based film to form from an interchange reaction at any pH below 7.0. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art to ascertain which pH below 7.0 will allow the interchange reaction by the free sulfhydryl groups of the modified protein to form disulfide bonds between the proteins to form a film. Thus for the instant claimed invention, it would require an undue burden of experimentation for a skilled artisan to determine exactly which pH value will allow the interchange reaction to occur and initiate film formation.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the

relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case the quantity of experimentation would be large since any pH below 7.0 can be chosen, i.e. pH 2, 1, etc. The amount of guidance is minimal with regard to which pH range below 7.0 will initiate film formation. On page 9 of the specification, Applicants disclose suitable pH for film formation can be in the range of pH 4.5-7.0 where the most efficient pH for the interchange reaction is about 3.5 (p. 9 lines 11-13). In Example 11, Applicants further disclose emulsions of film formation at pH 3.5 (p. 25). The nature of the invention is such that a change in the pH environment may disrupt the interchange reaction and the film formation process. It should be noted that the pH 2.0 is disclosed as a pH to test the acid resistance of the protein-based film (p. 24 Example 8). The state of the prior art is that proteins are sensitive to their environment and any changes to their physical environment may disrupt their activity. The relative level of skill in this art is very high. The predictability as to which pH values above 7.0 will confer an interchange reaction and initiate film formation is zero.

When the factors are considered in their entirety, the Wands analysis dictates a finding of undue experimentation and thus, the claim is not enabled.

Claims 1-5, 11-16, 18-26, 30-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art to ascertain proteins can form a disulfide bond network to form a film. Thus for the instant claimed invention, it would require an undue burden of experimentation for a skilled artisan to determine exactly proteins contain –SH groups (cysteine residues) since as currently written, the claims are directed to any protein of any structure.

The Wands factors are summarized above.

In the instant case the quantity of experimentation would be large since the claims are directed to any protein of any structure. The amount of guidance is minimal with regard to which proteins can form a disulfide bond network to form a film. In Example 1, Applicants disclose using whey protein as the modified protein in solution to activate lactalbumin (p. 20). However, the nature of the invention is such that the protein structure is essential to forming the disulfide bond network. The state of the prior art is that even proteins that are 99% similar to the wild-type protein are at times not fully active. The relative level of skill in this art is very high. The predictability as to what substantially similar protein will have which activity is zero.

When the factors are considered in their entirety, the Wands analysis dictates a finding of undue experimentation and thus, the claim is not enabled.

Claims 1-5, 11-16, 18-26, 30-34 are rejected under 112 first paragraph because it refers to proteins only by function.

The court of Appeals for the Federal Circuit has recently held that such a general definition does not meet the requirements of 35 U.S.C. 112, first paragraph. "A written

description of an invention involving chemical genus, like a description of a chemical species, requires a precise definition, such as be structure, formula {or} chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.,* 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel,* 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). The court held that "in claims involving chemical materials, generic formulae usually indicate with specificity what generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish it from others. One skilled in the art therefore cannot, as one can do with a fully described genus visualize the identity of the members of the genus". Here, Applicants are claiming proteins by what it does, i.e. function, rather than what it is, i.e. in terms of structure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 11-16, 18-26, 30-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 20 (and their dependent claims) are generally confusing. The claims recite a protein network formed by disulfide bonds between the proteins comprising a protein network

formed by disulfide bonds between the proteins comprising a protein network. It is unclear what is meant by proteins comprising a protein network because a protein network usually means that the network is made of proteins. Further, it is unclear what is "modified protein in solution." It is unclear if the treated proteins and the modified proteins are referring to the same set of proteins or to two different types of proteins. Applicants are asked to clarify between the different types of proteins in claims 1 and 20, i.e. proteins in the network, proteins comprising a protein network, modified proteins. Further, it is unclear if the interchange reaction is taking place between the modified proteins in solution or if they are between the network proteins or if they are between the network proteins and the modified proteins. Additionally, claim 20 recites forming said solution into said protein-based film. It is unclear what is meant by forming said solution into said protein-based film, i.e. solidifying solution to form a film. Further clarification is requested.

Claim 1, line 7, recites the limitation "the pH" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Regarding claims 4-5, 26, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 11 and 30 recite a substance to coat the substance. It is unclear what these substances are and whether if the first substance is the same as the second substance. Further clarification is requested.

Regarding claim 13, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claims 15 and 34 recite lipophilic compound. The claims are unclear because neither the claims nor the specification define and/or identify a lipophilic compound.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 11-16, 18-26, 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krochta et al. (US 5543164) in view of Krochta et al. (US 6869628).

Krochta et al. ('164) disclose water-insoluble protein-based coatings and films and methods for their preparation (col. 4 lines 33-35). Krochta et al. ('164) disclose the first step is the formation of an aqueous denatured protein solution (col. 5 lines 12-13). Preferred proteins include whey protein (col. 5 lines 22-23). The thiol-disulfide exchange can be effected by a chemical treatment or an enzymatic treatment (col. 5 lines 25-26). When a chemical treatment is used, the protein is brought into contact with a chemical agent for a period of time sufficient to initiate disulfide arrangements, wherein the chemical agents include sulfites (col. 5 lines 37-43). Further, thiol-disulfide exchange in a protein can also be performed enzymatically (col. 5 lines 47-48). The result of these reactions is a solution of a denatured protein having a mixture of

intermolecular and intramolecular disulfide crosslinks (col. 5 lines 51-53). Krochta et al. ('164) do not teach a mixture of denatured and non-denatured proteins to form a protein-based film.

Krochta et al. ('628) disclose methods of making water-insoluble films and coatings from water based WPI (whey protein isolate) solutions (col. 5 lines 3-5). Krochta et al. further disclose that mixtures of various proportions of denatured and non-denatured proteins can be used to impart any desired level of protection from moisture (col. 5 lines 11-14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a whey protein-based film by chemical and/or enzymatic treatment according to the teachings of Krochta et al. ('164) and mixing in various proportions of denatured and non-denatured whey protein as suggested by Krochta et al. ('628) in order to create a protein-based film and/or coating with the desired level of protection (claims 1-5, 20-26). The motivation to do so is given by Krochta et al. ('628) which teach that mixtures of various proportions of denatured and non-denatured proteins can be used to make protein-based films and/or coatings with levels of protection, i.e. moisture.

While Krochta et al. ('164) do not teach a pH of 7, Krochta et al. ('164) disclose that the enzymatic treatment can be carried out with enzymes including sulfhydryl oxidase, peroxidase, which function optimally at a pH of 7 (claims 1, 20).

Krochta et al. ('628) also disclose a method of providing an edible coating to a food comprising coating said food with a protein-based film (col. 23 lines 50-55).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the protein-based film of Krochta et al. ('164) in view of Krochta et al. ('628) on a food product because Krochta et al. ('628) suggest that an edible protein-based coating can

be used to coat food to make it more appealing or to protect it from moisture (claims 11-16, 18-19, 30-34).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

September 27, 2007

M. Monshi
MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER